K103068

Eminent Spine, LLC

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Phone: (512) 868-5980 Fax: (512) 864-1462

JAN 14 2011

8. 510(k) Summary

Date:	15 October 2010
Sponsor:	Eminent Spine LLC 7200 N I-35 Building #1 Georgetown, TX 46037 Phone 512-868-5980 Fax 512-864-1462
Contact Person:	Dave Freehill, President
Proposed Trade Name:	King Cobra™ Cervical Plate System
Device Classification	Class II
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation:	888.3060
Device Product Code:	KWQ
Device Description:	The King Cobra™ Cervical Plate System consists of self-tapping screws and plates. Screws are available in a variety of diameter-length combinations. Plates are available in a variety of lengths.
Intended Use:	The King Cobra™ Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.
Materials:	The King Cobra™ Cervical Plate System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.
Predicate Devices:	Cervical Spine Locking Plate (K945700/K030866)

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Technological Characteristics:	The King Cobra™ Cervical Plate System possesses the same technological characteristics as the predicate. These include • basic design (plate-based fixation system having self-tapping screws in various sizes), • material (titanium alloy), • sizes (plate and screw sizes are encompassed by those offered by the predicate systems) and • intended use (as described above). The fundamental scientific technology of the King Cobra™ is the same as the previously cleared device.
Performance Data:	Static compression bending and torsion, and dynamic compression bending of the worst case King Cobra™ construct was performed according to ASTM F1717. The mechanical test results demonstrated that King Cobra™ performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Eminent Spine, LLC
% Backroads Consulting, Inc.
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026-2141

JAN 14 2011

Re: K103068
Trade/Device Name: King Cobra™ Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 15, 2010
Received: October 18, 2010

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Indications for Use Statement

510(k) Number: K103068

Device Name: **King Cobra™ Spinal System**

Indications for Use:

The King Cobra™ Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103068